

Remarks

In view of the above amendments and the following remarks, reconsideration and further examination are respectfully requested.

Claims 1-12 and 18-19 have been canceled without prejudice. Claim 21 has been amended, and claims 34-40 have been added. Consequently, claims 13, 14-17, and 20-40 are currently pending and under consideration.

No new matter has been added with these amendments. For example, support for the amendments to claim 21 can be found on pages 5-6 of the specification and FIG. 1 of the drawings as well as elsewhere throughout the application. As another example, support for new claims 34-40 can be found on pages 4-6, 8 and 13-14 of the specification, and FIG. 1 of the drawings as well as elsewhere in the application.

Drawing Objections & Claim Rejections Under 35 U.S.C. §112

The drawings were objected to in item 1 of the Office Action for not showing “every feature of the invention specified in the claims.” Specifically, it was required that the “V-shaped cross-section” as claimed in Claim 21 must be shown or the feature(s) canceled from the claims(s).” In item 3 of the Office Action, claim 21 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Without conceding the basis of these objections/rejections and in order to speed prosecution, claim 21 has been amended to recite “wherein the channel-shaped area has an essentially rectangular-shaped cross-section.” This feature is supported by the application as originally filed. For instance, the last sentence on the bottom of page 6 of the present application states “[t]he cross-section of the capillaries can for example be V-shaped, semi-circular or also rectangular.” As recognized in item 3 of the Office Action, the drawings clearly show a rectangular shaped channel. In view of the above, it is requested that the objection of item 1 and the rejection of item 3 be withdrawn.

Independent Claim 13

In item 7 of the Office Action, independent claim 13 was rejected under 35 USC 103(a) as being unpatentable over Garcia et al. (US 4,637,403) in view of Yassinzadeh et al. (US 5,700,695). In traversal, the Applicants submit that a *prima facie* case of obviousness has not been established because even when combined together Garcia et al. and Yassinzadeh et al. fail

to disclose all of the features recited in independent claim 13. In addition, except through impermissible hindsight, there is no motivation to modify the cited references to arrive at the combination of features recited in claim 13 because Yassinzadeh et al. teaches away from making such a combination.

As noted above, Garcia et al. and Yassinzadeh et al. together fail to disclose all of the features recited in claim 13. For example, both references fail to disclose “the at least one capillary channel is open to the outside in an area which comprises at least a part of the longitudinal extension of the capillary structure extending beyond the distal end.” It was recognized on page 5 of the Office Action that “Garcia et al. however fails to disclose the at least one capillary channel is open to the outside which comprises at least a part of the longitudinal extension of the capillary structure extending beyond the distal end.” Nevertheless, it was alleged on page 6 that “Yassinzadeh et al, as discussed above, disclose a lancing device and further disclose the at least one capillary channel is open to the outside in an area which comprises at least a part of the longitudinal extension of the capillary structure extending beyond the distal end.” As will be explained in greater detail below, Yassinzadeh et al. does not expressly or inherently teach that its needle cannula 8 is capable of drawing fluid via capillary action, and in fact, Yassinzadeh et al. teaches away from drawing fluid via capillary action.

Yassinzadeh et al. describes a sample collection apparatus 2 that includes a hollow needle cannula 8, which is molded into a base 4. “Needle cannula 8 is preferably made of stainless steel and has an axially extending cut-out 40 at its distal end” (column 4, lines 64-67). Looking at FIG. 1, the base 4 defines a thermal pressure chamber 26. Air is heated in the thermal pressure chamber 26 and cooled in order to create a vacuum that is used to draw blood into the apparatus 2. Nowhere does Yassinzadeh et al. expressly teach that the needle cannula 8 at the cut-out region 40 is capable of drawing fluid via capillary action. Thus, Yassinzadeh et al. does not expressly disclose a capillary structure with the capillary channel of the type recited in claim 1.

Moreover, there is no inherent disclosure of such missing features. For an element to be inherently disclosed, it must “necessarily be present in the thing described in the reference.” In re Robertson, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Indeed, inherency “may not be established by probabilities or possibilities . . . The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” 49 USPQ2d at 1951. Even assuming for argument’s sake that the cut-out 40 section of needle 8 in Yassinzadeh et al. might possibly be

able to draw fluid via capillary action in some circumstances, such is still not a necessary consequence of the disclosure of Yassinzadeh et al. so as to make the feature inherent to the disclosure. For instance, it is conceivable, and probably likely, that needle 8 at the cut-out 40 is incapable of drawing fluid via capillary action. Capillary action occurs when the adhesion of a liquid, such as body fluid, to the walls of the capillary channel is stronger than the cohesive forces between the liquid molecules. Adhesion of the liquid to the walls of the capillary channel causes the edge of the liquid to move upwards in the channel, and the surface tension acts to hold the surface of the liquid intact, so instead of just the edges moving upward, the whole liquid surface is dragged upward in the channel, thereby causing the liquid to be drawn via capillary action. It should be recognized that the properties of the material used along the walls of a channel and the geometry of the channel determine whether the channel is able to draw fluid via capillary action. Yassinzadeh et al. at column 4, lines 66-67 only briefly mentions that “[n]eedle cannula 8 is preferably made of stainless steel” but this alone does not give the cut-out 40 of the cannula the ability to draw fluid via capillary action. Whether or not stainless steel is able to draw liquid via capillary action depends on how the stainless steel is processed or treated. For instance, it is conceivable that the stainless steel for the needle cannula 8 could have been treated in such a manner that needle cannula 8 was hydrophobic, and thus, unable able to draw fluid via capillary action. Indeed, when explaining the physics surrounding the conditions for drawing fluid via a vacuum, Yassinzadeh et al. at column 6, lines 55-67 only gives an example where the fluid passage is hydrophobic, and thus the fluid passage would not draw fluid via capillary action. Moreover, it is likely that the geometry of the cut-out 40 prevents body fluid from being drawn via capillary action. Yassinzadeh et al. at column 5, lines 2-3 teaches that “the radial depth of cut-out 40 is about 50% of the outside diameter of the needle 8.” With the cut-out having a radial depth of about 50%, it is likely that the overall contact area between the walls of the needle cannula 8 at the cut-out 40 and the surface of the body fluid is reduced to such an extent that the needle cannula 8 at cut-out 40 is unable to draw fluid via capillary action. Given that the cut-out 40 region of the needle cannula 8 does not necessarily draw fluid via capillary action, the open capillary channel as recited in claim 13 is not an inherent feature of Yassinzadeh et al.

Moreover, such a feature would not be obvious in view of Yassinzadeh et al. because Yassinzadeh et al. explicitly teaches away from using capillary action to draw fluid. As an illustration, Yassinzadeh et al. at column 1, lines 18-38 states:

While capillary action is quite simple, needing no moving parts, its usefulness is restricted when the materials of the sampling device are hydrophobic, thus precluding capillary action, or have mechanical discontinuities or configurations which create capillary stops, which can impede or halt capillary flow. Other problems can be created when relying on capillary flow; unintended secondary capillary channels along a wall having certain junctions can cause an element of unpredictability to the capillary flow in the main channel. To change the hydrophobic nature of a surface, a wetting agent or surface treatment, such as plasma etching or corona etching, can be applied to the hydrophobic surface to permit capillary action to occur. However, this raises the cost and complexity of the device, and could create contamination of the sample or introduce a deleterious agent into the patient. The problem of capillary stops can be addressed; however, solutions to eliminating capillary stops can require additional parts or very careful manufacturing techniques, both of which increase the cost of the device.

Instead of utilizing capillary action to draw fluid, Yassinzadeh et al. teaches that its sample collection apparatus 2 draws the fluid by creating a vacuum in the thermal pressure chamber 22. After reading Yassinzadeh et al., one skilled in the art would clearly be motivated away from using capillary action to draw fluid (see also, column 9, line 62 to column 10, line 5). Thus, there is no proper motivation to combine Garcia and Yassinzadeh et al. to arrive at the features recited in claim 13.

The Applicant also wishes to help clarify an issue raised in the Office Action. In particular, it was alleged on page 6 that “it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the open channel of the capillary structure from the distal end to the proximal end because the Applicant has not disclosed that the open channel from the distal end to the proximal end provides an advantage, is used for a particular purpose, or solves a stated problem.” The Applicant wishes to point out that the present application has already described that the open channel structure provides numerous advantages. By way of non-limiting examples, as explained on pages 5 and 12 as well as elsewhere in the application, having the capillary structure open helps to simplify manufacturing, thereby allowing the unit to be less expensive in comparison to conventional needles. Forming conventional needles, especially ones miniaturized to reduce pain, requires complicated and expensive manufacturing

processes. As discussed on pages 5-6 of the present application, conventional hollow needles are manufactured by drawing thick tubes, which can be very laborious and costly, especially when forming miniaturized needles. It is desirable to miniaturize the needles because it minimizes the size of the puncture wound, thereby reducing pain caused by lancing, as is noted on pages 2-3 of the application. In contrast to the difficulties in miniaturizing conventional hollow needles, the open capillary design described in the present application is relatively easy to manufacture. For instance, with the channel being open, the open channel can be easily formed by milling or by photolithography, to name a few examples. In the past, it was thought the capillary channel had to be closed in order to effectively draw fluid via capillary action. However, as discussed on page 6, it was discovered that it was in fact possible to achieve efficient uptake of body fluid even with an open capillary. In other words, having the capillary channel open allows the unit to be miniaturized in a cost effective manner, thereby providing an inexpensive device that creates minimal pain; while at the same time enlarges the available opening size to collect body fluid from the skin's surface. It should be appreciated that the needle 8 in Yassinzadeh et al. does not provide such advantages because the needle has to be manufactured using the laborious conventional manner (such as via drawing a tube), and then the section 40 is cut out of the needle 8.

For these and other reasons, independent claim 13 and its dependent claims are allowable over the references of record.

Claim 13's Dependent Claims

In addition to the reasons given above as to the patentability of independent claim 13, other reasons support the patentability of its dependent claims. In item 7 of the Office Action, dependent claim 14 was rejected under 35 USC 103(a) as being unpatentable over Garcia et al. in view of Yassinzadeh et al. Both of these references fail to disclose "the entire length of the capillary structure from the proximal to the distal end is open to the outside." As noted in the Office Action, Garcia fails to disclose an open capillary channel. Likewise, Yassinzadeh et al. does not disclose a capillary structure that is open along its entire length. Even assuming for the sake of argument that the needle 8 in Yassinzadeh et al. draws fluid via capillary action (which the Applicant does not believe to be true), the entire length of the needle 8 is not open to the outside. Looking at FIGS. 1 and 2, a large section of the needle 8 is closed, and the cut-out 40

only occupies a small fraction of the needle 8. After reviewing Yassinzadeh et al., one of ordinary skill in the art would have been motivated to keep most of the needle closed, because if the entire needle 8 was open, the sample collection apparatus 2 would have trouble drawing fluid via a vacuum. Instead of fluid being drawn, air would be drawn into the open, upper end of the needle 8. By way of analogy, it would be like trying to sip water through a straw that has a large hole above the water line. Without having the ability to draw fluid with a vacuum, the intended function of the sample collection apparatus 2 in Yassinzadeh et al. would be destroyed or at best significantly hampered. Given that both references fail to disclose the features recited in claim 14 and fail to provide any motivation to arrive at the recited feature, it is believed that dependent claim 14 is allowable over the references of record.

Independent Claim 24

In item 5 of the Office Action, independent claim 24 was rejected under 35 USC 102(b) as being anticipated by Yassinzadeh et al. However, claim 24 is clearly not anticipated by Yassinzadeh et al. For instance, Yassinzadeh et al. fails to disclose, either expressly or inherently, that “a capillary structure having a lancing tip configured to cut an incision in skin, the lancing tip defining a capillary groove for drawing the body fluid from the incision to the detection zone via capillary action, wherein the capillary groove opens longitudinally along the outside of the lancing tip to permit collection of the body fluid along the length of the lancing tip” as recited in claim 24. As discussed above, Yassinzadeh et al. does not expressly disclose that the cut-out section 40 of the needle 8 is configured to draw fluid via capillary action. In addition, Yassinzadeh et al. does not inherently disclose that the cut-out section 40 of the needle 8 draws fluid via capillary action because it is conceivable that the cut-out section 40 would not be able to draw fluid via capillary action but would instead rely upon a vacuum to draw fluid. Based on the comments made at column 6, lines 61-67, it is quite possible that the needle 8 in Yassinzadeh et al. is made from a hydrophobic material that is incapable of drawing fluid via capillary action. In addition, with the cut-out 40 being 50% of the outside diameter of the needle 8, it is unlikely that the needle 8 at the cut-out 40 could be able to draw fluid via capillary action. Furthermore, claim 24 would not be rendered obvious in view of Yassinzadeh et al. (in combination with other references) because one skilled in the art would not be motivated to draw fluid with a capillary channel. To reiterate, Yassinzadeh et al. explicitly teaches away from

using capillary action to draw fluid, and instead, it promotes the use of a vacuum. For these and other reasons, independent claim 24 and its dependent claims are allowable over the references of record.

Independent Claim 34

It is believed that new independent claim 34 is allowable over the references of record. For example, Yassinzadeh et al. fails to disclose or suggest that “the holding area and the lancing tip being a monolithic structure” and “the capillary groove opening along the surface of the holding area from the distal end of the lancing tip to the detection zone for transporting the body fluid via capillary action to the detection zone, the capillary groove being uncovered along the entire length of the lancing tip to permit collection of the body fluid along the entire length of the lancing tip” as recited in claim 34. As should be recognized, forming a groove in a monolithic piece is a relatively simple process, and thus, the recited disposable lancing device is relatively inexpensive to manufacture. Moreover, such a construction enhances fluid collection because fluid can be drawn from the surface of the skin. Looking at FIG. 1 of Yassinzadeh et al., the base 4 and the needle 8 of the sample collection apparatus 2 are separate components, and thus, not monolithic. Moreover, the sample collection apparatus 2 does not have an open groove that extends from the sharpened distal end 12 to the measurement chamber 26. Rather, a large part of the needle 8 is conventionally enclosed and therefore lacks a groove. Moreover, as explained above, the needle 8 in Yassinzadeh et al. is not open along its entire length, and Yassinzadeh et al. teaches away from such a feature because it would significantly hamper or render inoperative the sample collection apparatus 2 in Yassinzadeh et al. that utilizes a vacuum to draw fluid. Given that the cited references, even when combined together, fail to disclose all of the features recited in claim 34 and there is no proper motivation to arrive at the recited features, it is submitted that claim 34 and its dependent claims are allowable over the references of record.

February 11, 2005 Information Disclosure Statement

Again, it should be noted that an Information Disclosure Statement (IDS) was submitted on February 11, 2005. A copy of the IDS has not been again supplied since it appears on both public and private PAIR. It is respectfully requested that an initialed copy of this IDS be returned in the next communication from the Patent Office.

Supplemental Application Data Sheet

A Supplemental Application Data Sheet (ADS) was submitted with the last response (August 22, 2005) in order to update the spelling of an inventor's first name as well as to update the docket number, power of attorney and correspondence address information. In particular, it was requested that the attorney docket number be changed to "7404-727". In addition, it was requested that the first name for Mr. Koehler be corrected to "Karl-Heinz." In accordance with MPEP 201.03 and 601.05, it was believed that the ADS satisfied the requirements to correct the spelling of an inventor's name, and therefore, a supplemental declaration was not required. A Notice of Acceptance of Power of Attorney has been received in which the power of attorney and correspondence address was updated. However, the attorney docket number has not been updated, and based on the publication review information on private PAIR, it does not appear that Mr. Koehler's first name has been updated. In accordance with the August 22, 2005 ADS, it is respectfully requested that the USPTO update its records with respect to the attorney docket number and Mr. Koehler's first name.

Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early notice of allowance is earnestly solicited. If after reviewing this amendment the Examiner feels that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the undersigned representative by telephone to resolve such issues.

Respectfully submitted,

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